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November 15, 2013

Dania Zinner
USEPA; Region 8
1595 Wynkoop Street (8EPR-SR)
Denver, CO 80202-1129

Document ID #: 3019-11152013-4

Dear Ms. Zinner:

EPA CONTRACT NUMBER EP-W-10-033
TASK ORDER NUMBER 3019
QA SUPPORT FOR THE LIBBY ASBESTOS SITE

Enclosed please find the Summary Asbestos On-site Audit Report for the on-site audit performed on October 8, 2013 at EMSL Analytical, Inc. in Cinnaminson, New Jersey. This report and the accompanying checklist are deliverables under Task 5 of the subject Task Order.

If you have any questions, please feel free to contact me.

Sincerely,

Timothy Vonnahme

Timothy L. Vonnahme
Audit Group Manager, QATS Program
CB&I Federal Services, LLC
Phone: (702) 895-8729
E-Mail Address: timothy.vonnahme@cbifederalservices.com

cc: Administrative Contracting Officer (letter only)
Audit Group Files

REPORT

FOR

TASK ORDER NUMBER 2019
QUALITY ASSURANCE SUPPORT FOR THE LIBBY ASBESTOS SITE

SUMMARY ASBESTOS ON-SITE AUDIT REPORT

EMSL Analytical, Inc. (Cinnaminson, NJ)

Prepared by:

The Data Auditing Group
Quality Assurance Technical Support Program
CB&I Federal Services, LLC
2700 Chandler Avenue
Las Vegas, Nevada 89120

November 14, 2013

QATS Contract Number: EP-W-10-033

Prepared for:

Dania Zinner
Task Order Manager

Region 8
U.S. Environmental Protection Agency
1595 Wynkoop Street
Denver, CO 80202

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LABORATORY INFORMATION AND AUDIT SCOPE

This report summarizes the results of an asbestos on-site laboratory audit of the EMSL Analytical, Inc. in Cinnaminson, New Jersey performed on October 8, 2013. The audit was conducted in support of the United States Environmental Protection Agency (EPA) Region 8 Libby Superfund Site activities. The purpose of the audit was to evaluate corrective actions taken by the laboratory to address deficiencies identified from the last on-site audit conducted on June 26-27, 2012. CB&I Federal Services, LLC Quality Assurance Technical Support (QATS) staff participation in the on-site audit and subsequent preparation of this report was performed under Task 5, Task Order 2019, QATS Contract EP-W-10-033.

Detailed information regarding the subject laboratory is as follows:

Date of On-site:	**October 8, 2013**
Laboratory:	**EMSL Analytical, Inc.** **200 Route 130 North** **Cinnaminson, NJ 08077** **(800) 220-3675**
Special Projects Manager:	**Robyn Denton**
Audit Team	
US EPA:	**Dania Zinner (by teleconference)**
CB&I QATS:	**Michael Lenkauskas, CQA, Senior Auditor**

The Audit Team, comprised of CB&I Federal Services, LLC QATS personnel, performed the technical and evidentiary aspects of the on-site audit. Due to unforeseen circumstances, a representative of the EPA was not able to attend but participated in the debriefing via conference call. The technical and evidentiary parts of the audit involved an evaluation of corrective actions taken by the laboratory to address the deficiencies identified during the previous on-site audit conducted on June 26-27, 2012.

Processes evaluated included sample receipt, sample storage, sample tracking, sample preparation for Transmission Electron Microscopy (TEM) analysis, analysis by Polarized Light Microscopy (PLM), and Quality Assurance/Quality Control (QA/QC). All pertinent laboratory instrumentation and equipment were inspected for proper maintenance and calibration, and laboratory personnel were interviewed to determine their understanding and adherence to laboratory procedures.

During the course of the audit, the applicable sections of the Libby-Specific Asbestos Laboratory On-site Audit Checklist were completed by the Audit Team. Sections of the checklist not completed during the audit are indicated with an “NA.” The checklist is provided as an attachment to this report (EPA only).

EXECUTIVE SUMMARY

An asbestos laboratory on-site audit of EMSL Analytical, Inc. in Cinnaminson, New Jersey was performed on October 8, 2013 in support of EPA Region 8 Libby Superfund Site activities. The primary focus of the audit was to evaluate the corrective actions taken by the laboratory to address the deficiencies identified during the previous on-site audit conducted on June 26-27, 2012. The laboratory areas and processes evaluated included sample receipt, sample storage, sample tracking, sample preparation for Transmission Electron Microscopy (TEM) analysis, analysis by Polarized Light Microscopy (PLM), and Quality Assurance/Quality Control (QA/QC).

Corrective actions in response to the previous audit the seven deficiencies identified in the June 2012 on-site audit were evaluated during the current on-site audit. The Audit Team determined that the laboratory had completely addressed all seven, for a corrective action rate of 100%.

The on-site audit identified three new deficiencies which are summarized below by laboratory area:

Indirect and Direct Preparation of Air Filter and Dust Samples – One deficiency was assessed due to a lack of personnel with the training necessary to prepare duff and tree bark samples for analysis by TEM.

Polarized Light Microscopy (PLM) Analysis – Two deficiencies were assessed for failure on one of the PLM microscopes to utilize the correct 550 nm compensator plate specified in the project-specific procedure, and failure to submit completeness checklists with the PLM-VE and PLM-GRAV data packages.

With the exception of the deficiencies noted above, the on-site evaluation revealed EMSL Analytical, Inc. in Cinnaminson, New Jersey to have sufficient facilities, equipment, and staff to analyze samples in accordance with the specified methodologies and Libby-specific protocol. All staff and management were cooperative, readily answered all questions asked by the Audit Team, and appeared to be responsive to the identified deficiencies.

AUDIT FINDINGS

Sample Receipt, Storage, Log-in, and Chain-of-Custody (COC)

The evaluation of this area focused on the one deficiency identified in the previous on-site audit, which was found to have been adequately addressed. No additional deficiencies were observed.

Indirect and Direct Preparation of Air Filter and Dust Samples

The evaluation of this area focused on the one deficiency identified in the previous audit. The deficiency has been addressed as described in the section "Corrective Action Applied from the Previous Audit Deficiencies" on Page 6 of this report. One new deficiency was identified:

1. With the departure of a key staff member, the laboratory no longer has adequate personnel with the training necessary to prepare duff and tree bark samples for analysis by TEM. The training requirements for laboratory personnel are described in Section 4.2.3.3 of the Site-wide Quality Assurance Reference Document (QARD, Rev. 0) and Section 5.2.2 of the laboratory's Quality Assurance Manual (QAM). (Checklist Nos. 6.1 and 10.2.1)

   Note: The laboratory has not received tree bark or duff samples since the departure of this key staff member.

   Recommended Corrective Action – Ensure that properly trained personnel are available for the preparation of tree bark, duff, and other sample media received from the Libby Superfund site.

Transmission Electron Microscopy (TEM) Analysis

No issues were identified in this area during the previous on-site audit; however, an evaluation of this area was performed during the current audit to assess the knowledge of a newly trained TEM analyst. No new deficiencies were identified.

Polarized Light Microscopy (PLM) Analysis

The evaluation of this area focused on the four (4) deficiencies identified in the previous audit. These deficiencies have been addressed as described in the section "Corrective Action Applied from the Previous Audit Deficiencies" on Page 6 of this report. Two new deficiencies were identified:

2. One of the PLM microscopes used to analyze Libby samples incorrectly utilized a 530 nm compensator plate, rather than a 550 nm compensator plate as specified in the Libby project-specific procedure. Although this deviation is recorded on the bench sheet, it is not described in sufficient detail and is not described in the applicable data package narratives. The requirement to use a 550 nm compensator plate is described in Section 10.3.1.12 of both the PLM-VE (SRC-Libby-03, Rev. 3) and PLM-Grav (SRC-Libby-01, Rev. 3). (Checklist Nos. 8.6.1.12 and 8.15.1)

   Recommended Corrective Action – Ensure all deviations from project-specific requirements are described in sufficient detail in the applicable data package narratives.

3. The laboratory was not including the data package completeness checklists with the data deliverables. These checklists are provided with both the PLM-VE and PLM-GRAV EDD templates. The requirement to provide a competed checklist with each PLM-VE, PLM-GRAV, and NIOSH 9002 hardcopy (scanned) data deliverable is described in the "Data Pkg Checklist" tab of each of the applicable EDD templates. (Checklist No. 9.1.2.2)

   Recommended Corrective Action – Ensure that data package checklists are provided with each PLM-VE, PLM-GRAV, and NIOSH 9002 hardcopy deliverable.

Data Management

This area was not evaluated since there were no data management issues identified in the June 2012 audit.

Quality Control and Quality Assurance (QA/QC)

The evaluation of this area focused on the one deficiency identified in the previous on-site audit, which has been adequately addressed. No additional deficiencies were observed.

CORRECTIVE ACTION APPLIED FROM THE PREVIOUS AUDIT FINDINGS

The on-site laboratory evaluation included an assessment of the seven (7) deficiencies identified and reported in the previous on-site audit performed on June 26-27, 2012. The Audit Team determined that the laboratory had completely addressed all seven findings (100.0%). The following are the deficiencies identified during the previous on-site audit, the laboratory's verbatim responses to the audit finding comments, and effectiveness checks performed during the current on-site audit.

Sample Receipt, Storage, Log-in, and Chain-of-Custody (COC)

1. Samples prepared or partially prepared at other EMSL facilities (i.e., Libby, MT) and transferred to EMSL in Cinnaminson, NJ (where sample preparation is completed and/or samples are analyzed) are not shipped under proper COC. The identity of the individual relinquishing and receiving the samples and the dates on which samples are relinquished and received at the EMSL laboratory are not recorded on the EMSL internal COC. The requirement that sample custody be maintained from sample collection though analysis is described in Section 5.8.1 of the laboratory's QAM. (Checklist Nos. 4.2.4.1 and 4.2.4.2)

   Recommended Corrective Action – Ensure that sample custody, specifically of prepared samples transferred from one EMSL facility to another, is properly maintained.

   Laboratory Response (08/13/2012): *The samples that were received at EMSL Cinnaminson were Repreparations of samples that the EMSL-Libby lab had previously submitted. The samples were submitted with a new prep log; however, no documentation of custody was transferred with the samples. The Libby Laboratory was not aware that beyond the original transfer of samples, all re-preparations should also be transferred under the same conditions. Further training was required. Robyn Denton spoke with Ron Mahoney, Lab Manager at EMSL, Libby, about transferring all samples, including re-preparations, under the appropriate Chain of Custody. Both are in agreement of the procedures going forward. Charles LaCerra of Cinnaminson Log In department is monitoring compliance.*

Results of Root Cause Analysis: *The samples that were received at EMNSL Cinnaminson were re-preparations of samples that the EMSL-Libby Lab had previously submitted. The samples were submitted with a new prep log; however, no documentation of custody was transferred with the samples. The Libby Laboratory was not aware that beyond the original transfer of samples, all re-preparations should also be transferred under the same conditions. Further training was required.*

Statement of Action/Proof of Commitment: *Robyn Denton spoke to Ron Mahoney, Lab Manager at EMSL, Libby, about transferring all samples, including re-preparations, under the appropriate Chain of Custody. Both are in agreement of the procedures going forward. Charles LaCerra of Cinnaminson Log In department is monitoring compliance.*

Evidence of Compliance: *Please see attached Inter-Laboratory Sample Transfer Inventory package including internal chain of custody (EMSL Order ID: 271200324) for recently transferred samples.*

Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

Indirect and Direct Preparation of Air Filter and Dust Samples

2. The top loading balance used to weigh duff and tree bark samples is certified annually; however, it is not calibrated daily or when used. Laboratory management explained that they were having a difficult time acquiring a reference weight representative of a typical tree bark or duff sample, which would be approximately 300 grams. The requirement that balances be calibrated (verified) each day before first use is described in Section 8.2 of the laboratory's balance calibration SOP. (Checklist Nos. 6.4.4.1 and 8.4.4.2)

   Recommended Corrective Action – Ensure that balances used to weigh samples are calibrated each day before first use.

   Laboratory Response (08/13/2012): *The micro analytical balance weights that are currently used in the asbestos bulk preparation lab were too low to be viable verification weights for Duff and Bark samples. These weights are typically 2 g to 20g, while the weight of tree barks and Duff is typically around 300 g. Without having the proper weights to use we could not properly bracket the expected sample weights. Three additional weights have been purchased to bracket the expected weights of Bark and Duff: 30 grams, 200 grams, and 2000 grams. These weights were purchased with NIST traceable certificates. The certificates of the weights are attached in this PDF. The balance verification worksheet used for the pan balance is also attached, showing verifications done on the day that the duff and bark were dried and ashed.*

   Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

Transmission Electron Microscopy (TEM) Analysis

No observations concerning TEM were identified.

Polarized Light Microscopy (PLM) Analysis

3. Microscopes that have been moved from or replaced at a PLM work station are not documented in a manner which maintains traceability with the applicable maintenance and calibration logbooks. If equipment is moved or replaced from a work station, the

calibration and/or maintenance records remain at the work station. These logs are subsequently used to record calibration and maintenance activities of the replacement equipment. The requirement that a logbook be maintained for each piece of critical equipment and that all maintenance, repairs and calibrations be recorded along with the identity of the equipment is described in Section 5.5.1 of the laboratory's QAM. (Checklist No. 8.7)

Recommended Corrective Action – Ensure that all instrument maintenance, repairs, and calibrations are recorded and that any equipment moved from a work station is documented.

Laboratory Response (08/13/2012): *Recent scope additions were made to the PLM laboratory. These scopes were added to the Equipment Maintenance Log, however reference to older scopes that were put out of service were not longer represented. Going forward, the records associated with de-activated equipment will be stored in a separate spreadsheet dedicated to inactive equipment. The quality manager retrained our record custodian in the proper way to contend with obsolete electronic records. A current summary of equipment maintenance log for PLM is attached. This shows both active and inactive equipment. In the future the inactive equipment will be moved to a separate spreadsheet.*

Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

4. The laboratory is not currently performing the PLM analysis of fine ground soil samples as described in the Libby-specific SOP. The Libby-specific procedure, as outlined in SOP SRC-Libby-03, requires that suspect fibers be picked out prior to preparing five random slide mounts. The procedure demonstrated by the analyst involved the preparation of five random slides mounts followed by the removal of suspect fibers. The requirement that the laboratory supervisor ensure that all analyses are performed in accordance with the SOP and that the laboratory supervisor identify and take appropriate corrective action to address any deviations is described in Section 3.1 of the Libby-specific SOP for the Analysis of Fibers in Soil by PLM (SRC-Libby-03, Rev. 2). (Checklist Nos. 8.12.1.4 and 8.15.1)

   Recommended Corrective Action – Ensure that all analyses are performed in accordance with the procedures described in the Libby-specific SOP for the Analysis of Fibers in Soil by PLM.

   Laboratory Response (08/13/2012): *Analyst variability and preference. Re-training of Libby PLM analysts in the correct analysis order for Libby PLM VE samples. A copy of the training records for Nancy Stalter is included as an example of the training performed.*

   Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

5. The set of laboratory prepared, permanently mounted, LA reference slides of 0.2% and 1.0% were not prepared "in-house," but by one of the other Libby laboratories. The requirement that laboratories analyzing samples for LA prepare five slide-mounts from both the 0.2% and 1.0% LA reference materials in a permanent medium, such as epoxy or melt-mount, is described in Section 13.7.3.2 of the Libby-specific SOP for the Analysis of Fibers in Soil by PLM (SRC-Libby-03, Rev. 2). (Checklist No. 8.12.6.3)

Recommended Corrective Action – Ensure that a permanent set of laboratory-specific slide-mounts of the 0.2% and 1.0% LA for semi-quantitative estimation of LA in fine ground soil samples are prepared in-house.

Laboratory Response (08/13/2012): *The main PLM VE analysts felt that the permanent preps sent by Reservoirs Environmental, Inc were adequate in loading for our purposes. However, there were some instances, where less material was on the slide prep, in which case we prepared a temporary reference slide from the bulk soil reference standards using 1.625 refractive index liquid. EMSL has ordered Meltmount waxes from Cargille to prepare permanent slides in-house. We have computed that we would need 73% of the 1.605 and 27% of the 1.68 melt mounts to make the slides be at ≈1.625. Packing slip of meltmount waxes. We are in the process of mixing the meltmounts, however, this was not completed at the time the audit report was due. Once it is completed we will forward you evidence that the slides were made and are in use.*

Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

6. The Laboratory Duplicate Cross-check (LDC) analytical observations of optical properties are currently recorded on the same bench sheet as the observations of the original analysis and are, therefore, not "blind." The requirement that the original results be unknown when the second analysis is performed is described in Section A.5.9.3 of the laboratory's QAM. (Checklist No. 8.14.1)

   Recommended Corrective Action – Record LDC results on a separate bench sheet, other than that used to record the original results. Ensure that the results from the original analyses are unknown to the individual performing the second QC analysis.

   Laboratory Response (08/13/2012): *The recording of QC on the same sheet as the original analysis was a training issue. Some of the staff were aware that this needed to be done on a different bench sheet, while others were not. Re-training of Libby PLM analysts in the correct way to perform blind QC on a sample and how to record QC for Libby PLM VE samples. See attached EMSL order ID (041220397) showing the LDC and original analyses on separate analytical worksheets.*

   Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

Data Management

No observations concerning data management were identified.

Quality Control and Quality Assurance

7. The laboratory's process for tracking corrective actions that have either not been closed or that require follow-up is not adequate. Corrective actions are tracked on spreadsheets specific to the calendar quarter in which the corrective action was initiated; however, once a quarter has ended, the QAO does not review previous corrective action spreadsheets to determine the status of corrective actions initiated in previous quarters. The requirement for the QA department to ensure corrective actions are documented, addressed, and evaluated is described in Section 3.0 of the laboratory's SOP for Non-conformities and Corrective Actions. (Checklist No. 10.4.1)

Recommended Corrective Action – Ensure that corrective actions are tracked in a manner which ensures they are addressed and that follow-up is performed in a timely manner.

Laboratory Response (08/13/2012): *Mis-communication between the QAO and laboratory management lead to a delayed review and follow-up of Corrective actions. We have asked the QAO to prepare a list of outstanding corrective actions to the appropriate supervisor and laboratory management to ensure CARs are addressed and closed out in a timely manner. Completed corrective action reports for the first and second quarter.*

Effectiveness Check (10/08/2013): This deficiency has been completely addressed.

CONCLUSIONS

An asbestos laboratory on-site audit of EMSL Analytical, Inc. in Cinnaminson, New Jersey was performed on October 8, 2013 in support of EPA Region 8 Libby Superfund Site activities. The primary focus of the audit involved an evaluation of the corrective actions taken by the laboratory to address the deficiencies identified during the previous on-site audit conducted on June 26-27, 2012. The laboratory areas and processes evaluated included sample receipt, sample storage, sample tracking, sample preparation for Transmission Electron Microscopy (TEM) analysis, analysis by Polarized Light Microscopy (PLM), and Quality Assurance/Quality Control (QA/QC).

The Audit Team evaluated the corrective action applied to the seven deficiencies identified in the previous on-site audit, and determined that the laboratory completely addressed all seven, for a corrective action rate of 100%.

The on-site audit identified three new deficiencies:

- Lack of personnel trained to prepare duff and tree bark samples for analysis by TEM.
- Use of an incorrect compensator plate on one of the PLM microscopes used to analyze Libby samples.
- Failure to submit the PLM-VE and PLM-GRAV data package completeness checklists with the data packages.

With the exception of the three deficiencies noted above and in the report, the on-site evaluation revealed EMSL Analytical, Inc. in Cinnaminson, New Jersey to have sufficient facilities, equipment, and staff to analyze samples in accordance with the specified methodologies and Libby-specific protocol. All staff and management were cooperative, readily answered all questions asked by the Audit Team, and appeared to be responsive to the identified deficiencies.

ATTACHMENT

Libby-Specific Asbestos Laboratory On-site Audit Checklist (EPA Only)

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

Laboratory: EMSL Analytical, Inc.

Address: 200 Route 130 North

Cinnaminson, NJ 08077

Telephone: (800) 220-3675

Laboratory Personnel Contacted

Name	Title
Robert DeMalo	Senior Vice President
Robyn Denton	Special Projects Manager
Charles LaCerra	Special Projects/Sample Receiving Manager
Meghan Smollock	Data Coordinator
Leslie McClusky-Eissing	TEM/PLM Analyst
Melissa Klinedinst	Laboratory QC Group Leader
Garret Vliete	PLM Supervisor

Evaluation Team

Name	Title
Michael Lenkauskas, CQA	CB&I Federal Services, LLC (QATS), Senior Auditor

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

1.0 LABORATORY STATUS & CAPABILITIES	Yes	No	Comments
1.1 Which of the following capabilities does the laboratory possess:			
1.1.1 Phase Contrast Microscopy (PCM)?	☒	☐	
1.1.2 Polarized Light Microscopy (PLM)?	☒	☐	
1.1.3 Transmission Electron Microscopy (TEM)?	☒	☐	
1.1.4 Others (list)?	☐	☒	This is a full service laboratory.
1.2 Is the laboratory currently receiving samples from Libby Superfund Site Operable Units?	☒	☐	

If "**YES,**" complete the following table:

Operable Unit	Matrix/Method(s)	Project/Comments
The EMSL Cinnaminson laboratory has performed PLM and TEM sample analyses, on all sample matrices (i.e., air, water tree bark and duff) from all of the operable units, including OU3.		

2.0 LABORATORY SECURITY	Yes	No	Comments
2.1 Are visitors required to sign in?	☒	☐	
2.2 Are all entrances to the laboratory secured?	☒	☐	

Additional Comments:

3.0 PROJECT INITIATION/PROJECT MANAGEMENT	Yes	No	Comments
3.1 Are there designated project managers or a project management team to ensure samples received are properly processed?	NA	NA	
3.2 Are project-specific requirements and procedures communicated to laboratory staff:			
3.2.1 Project-specific SOPs?	☒	☐	Quality documents reside in the CDM eRoom where all EMSL analysts have access.
3.2.2 Laboratory Modifications?	☒	☐	
3.2.3 SAP Analytical Summaries?	☒	☐	
3.2.4 Project-specific Electronic Data Deliverables (EDDs)?	☒	☐	
3.2.5 Other (list)?	☐	☒	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

4.0 SAMPLE RECEIPT, LOG-IN, STORAGE, & TRACKING	Yes	No	Comments
4.1 Is the sample receiving area adequate, clean, and orderly?	☒	☐	

Personnel Interviewed

Name	Title	Experience
Charles LaCerra	Special Projects/Sample Receiving Manager	13 Years

4.2 Sample Receipt			
4.2.1 Is there a sample custodian and designated alternate responsible for sample receipt and log-in?	NA	NA	
4.2.2 Is the custodian or alternate available to receive and log-in samples at any time delivery services are operating?	NA	NA	
4.2.3 Are sample shipping containers opened in a HEPA hood (as necessary) to both minimize personal exposure and safeguard against laboratory contamination?	NA	NA	
4.2.4 Does the sample custodian verify and record the following when inspecting shipments and reviewing documentation:			
4.2.4.1 Presence and condition of custody seals?	☒	☐	
4.2.4.2 Presence or absence of Chain-of-Custody (COC) records?	☒	☐	
4.2.4.3 Presence or absence of air bill sticker(s)?	☒	☐	
4.2.4.4 Sample condition?	☒	☐	
4.2.4.5 Presence of packaging or packing material which could compromise samples (i.e., vermiculite & polystyrene)?	☒	☐	
4.2.4.6 Problems/discrepancies between samples, documentation, client requests, etc.?	☒	☐	
4.2.4.7 Bulk and air samples received separately?	☒	☐	
4.2.5 Are COC records signed and dated at the time of sample receipt?	☒	☐	
4.2.6 Is a system in place to ensure laboratory personnel are made aware of project specific requirements?	☒	☐	All personnel have access to the CDM eRoom.
4.2.7 Is a system in place to contact the client in case of absent documentation, or discrepancies between COCs, client requests, etc.?	NA	NA	
4.2.8 Are subsequent resolutions to problems and discrepancies documented?	NA	NA	
4.3 Sample Identification			
4.3.1 Are sample receipt identification logbooks, or a LIMS, used to log-in samples and assign unique laboratory identification numbers?	NA	NA	
4.3.1.1 Does the logbook or logging system serve as a direct cross-reference between laboratory ID numbers and client ID numbers?	NA	NA	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

4.0 SAMPLE RECEIPT, LOG-IN, STORAGE, & TRACKING	Yes	No	Comments
4.4 Sample Storage			
4.4.1 Are storage facilities sufficient?	☒	☐	Samples are shipped back to ESAT (TechLaw) in Libby.
4.4.2 Is the sample storage area secured to prevent entry of unauthorized personnel?	NA	NA	
4.4.3 Is a logbook or other means used to record sample locations?	NA	NA	
4.4.4 Are samples easy to locate from logbook references?	NA	NA	
4.5 Sample Tracking			
4.5.1 Is a system in place to keep track of samples entering and leaving the storage, sample preparation, and analysis areas?	NA	NA	
4.5.2 Are the retention and/or disposal of unused portions of samples and prepared samples documented?	NA	NA	
4.5.2.1 Are project-specific retention and/or disposal requirements communicated and followed?	NA	NA	
4.6 Standard Operating Procedures (SOPs)			
4.6.1 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?	☒	☐	All SOPs are available on the laboratory network.

Document Title	Control No.	Description
QA Manual	Rev. 15	Section 5.4.7.1.1 of Module A

4.7 Document Control:	Yes	No	Comments
4.7.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?	☒	☐	

Document Title	Description/Comments

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

5.0 PHASE CONTRAST MICROSCOPY (PCM)	Yes	No	Comments
5.1 Does the laboratory perform PCM analyses on samples received from the Libby Superfund site? ***If answered "No" precede to Section 6.0 of the checklist.***	☐	☒	
5.2 Is the PCM area adequate, clean, and orderly?	☐	☐	
5.3 Are steps taken to prevent the cross-contamination of equipment, supplies, and reagents?	☐	☐	

Personnel Interviewed

Name	Title	Experience

5.4 Methods and Guidance Documents	Yes	No	Comments
5.4.1 Are the applicable guidance documents available for reference:			
5.4.1.1 NIOSH Method 7400 (Issue 2), 1994?	☐	☐	
5.4.1.2 Other (list)?	☐	☐	
5.4.2 Are project-specific requirements communicated to laboratory personnel and available for reference:			
5.4.2.1 Laboratory Modification LB-000015A?	☐	☐	
5.4.2.2 SOP EPA-Libby-08?	☐	☐	
5.4.2.3 SAP Analytical Summaries?	☐	☐	
5.4.2.4 Project-specific Electronic Data Deliverables (EDDs)?	☐	☐	
5.4.2.5 Other (list)?	☐	☐	
5.5 Equipment			
5.5.1 Ventilation Hoods:			
5.5.1.1 Checked routinely and recorded in a permanent logbook?	☐	☐	
5.5.2 Are the microscopes used to analyze samples equipped with the following:			
5.5.2.1 Positive phase contrast, with green or blue filter?	☐	☐	
5.5.2.2 Adjustable field iris?	☐	☐	
5.5.2.3 Eyepiece (8 to 10X)?	☐	☐	
5.5.2.4 Phase magnification (40 to 45X)?	☐	☐	
5.5.2.5 Walton-Beckett Graticule?	☐	☐	
5.5.2.6 Stage micrometer with 0.01 mm subdivisions?	☐	☐	
5.5.3 Are microscope and phase ring alignment checks conducted daily?	☐	☐	
5.5.4 Is resolution periodically checked using an HSE/NPL slide?	☐	☐	
5.5.5 Are maintenance and calibration activities recorded in microscope-specific logbooks?	☐	☐	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

5.0 PHASE CONTRAST MICROSCOPY (PCM)	Yes	No	Comments
5.6 Sample Preparation			
5.6.1 Are filters prepared as described in the applicable method(s)?	☐	☐	
5.6.2 Are filters visibly overloaded (>25%) or contain loose debris prepared indirectly as described in SOP EPA-Libby-08?	☐	☐	
5.7 Sample Analysis			
5.7.1 Are the appropriate counting rules used (A or B)?	☐	☐	
5.7.2 How are the fields and fibers tracked and recorded? _____			
5.8 Quality Control			
5.8.1 Is each analyst provided a minimum of one reference slide per work day?	☐	☐	
5.8.2 Are recounts analyzed at a frequency of 1 per 10 samples analyzed?	☐	☐	
5.8.2.1 For count pairs not within acceptance limits are associated samples recounted?	☐	☐	
5.9 Standard Operating Procedures (SOPs)			
5.9.1 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?	☐	☐	

Document Title	Control No.	Description

5.10 Document Control	Yes	No	Comments
5.10.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?	☐	☐	

Document Title	Description/Comments

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	**Yes**	**No**	**Comments**
6.1 Are the grid preparation areas adequate, clean, and orderly?	☐	☒	Refer to Finding No. 1 in the Audit Report
6.2 Are bulk samples prepared in an area separate from that used to prepare air and dust samples?	☒	☐	
6.3 Are steps taken to prevent the cross-contamination of equipment, supplies, and reagents?	☒	☐	

Personnel Interviewed

Name	**Title**	**Experience**
Robyn Denton	Special Project Manager	13 Years

6.4 Equipment & Supplies	**Yes**	**No**	**Comments**
6.4.1 Ventilation Hoods:			
6.4.1.1 Checked routinely and recorded in a permanent logbook?	NA	NA	
6.4.2 Drying oven:			
6.4.2.1 Checked routinely and recorded in a permanent logbook?	NA	NA	
Note: Desiccator is an option for indirect preparation.			
6.4.3 Muffle furnace:			
6.4.3.1 Checked routinely and recorded in a permanent logbook?	NA	NA	
6.4.4 Analytical balances:			
6.4.4.1 Checked routinely and recorded in a permanent logbook?	☒	☐	
6.4.4.2 Calibrated within the last 12 months by a certified technician?	☒	☐	
6.4.5 Plasma Asher:			
6.4.5.1 Calibrated at least quarterly and recorded in a permanent logbook?	NA	NA	
Refer to Request for Modification LB-000085A			
6.4.6 Sputter Coater (Vacuum evaporator):			
6.4.6.1 Checked routinely and recorded in a permanent logbook?	NA	NA	
6.4.7 Filtration Apparatus (for indirect preparation):			
6.4.7.1 Are disposable or glass funnels used (record catalogue #)?	NA	NA	
6.4.7.2 Has the Effective Filtration Area (EFA) been determined and recorded for each apparatus?	NA	NA	
6.4.8 TEM Grids:			
6.4.8.1 Is documentation for average grid opening determination available?	NA	NA	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	Yes	No	Comments
6.5 Direct and Indirect Preparation Methodology			
6.5.1 What method(s) does the laboratory use to prepare air and dust samples for TEM analysis:			
6.5.1.1 40 CFR, Chapter 1, Part 763, Subpart E - AHERA?	NA	NA	
6.5.1.2 ISO 10312:1195 E - Determination of Asbestos Fibers?	NA	NA	
6.5.1.3 ASTM D 5755-09 - Micro vacuum Sampling and Indirect Analysis of Dust by TEM?	NA	NA	
6.5.1.4 Others (list)?	NA	NA	
6.5.2 Are project-specific requirements communicated to laboratory personnel and available for reference:			
6.5.2.1 Laboratory Modifications?	☒	☐	Quality documents reside in the CDM eRoom, to which all EMSL analysts have access.
6.5.2.2 Project-specific SOPs?	☒	☐	
6.5.2.3 SAP Analytical Summaries?	☒	☐	
6.5.2.4 Other (list)?	☐	☒	
6.6 Sample Inspection			
6.6.1 Are air filter cassettes carefully wet-wiped prior to being transferred to the clean preparation area for inspection?	NA	NA	
6.6.2 Are air filter samples which are visibly overloaded, exhibit uneven loading, or contain loose debris, prepared indirectly? *Refer to Laboratory Modifications LB-000016H & LB-000031G*	NA	NA	
6.6.3 Are all ambient air samples dried upon receipt at the on-site laboratory (i.e., EMSL-Libby) prior to preparation and analysis? *Refer to Laboratory Modification LB-000055A*	NA	NA	
6.7 Direct Preparation of MCE and Polycarbonate Filters			
6.7.1 Are MCE filters collapsed using either a Di-Methyl Formamide (DMF) or acetone atmosphere (AA) technique (describe technique)? *The use of an acetone vaporizer ("hot block") is not advised due to the formation of wind rows and tilted fibers.*	NA	NA	
6.7.2 Is plasma etching performed on collapsed MCE filters?	NA	NA	
6.7.2.1 Is a 5 to10% layer of the collapsed surface removed during etching?	NA	NA	
6.7.3 Are collapsed MCE filters and secured polycarbonate filters transferred to a vacuum evaporator for carbon coating?	NA	NA	
6.7.4 Are excised filter sections placed on the appropriately labeled TEM grids and cleared using a Jaffe Washer or an equivalent technique (describe)?	NA	NA	
6.7.5 Are samples checked for remaining filter residue after clearing?	NA	NA	
6.7.5.1 If residue remains, is condensation washing or an equivalent technique used (describe technique)?	NA	NA	
Additional Comments:			

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6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	Yes	No	Comments
6.8 Indirect Sample Preparation of Air and Dust Samples			
6.8.1 Are the applicable Libby guidance documents available for reference:			
6.8.1.1 SOP EPA-Libby-08 – Indirect Preparation of Air and Dust Sample for TEM Analysis?	NA	NA	
6.8.2 Sample filtration:			
6.8.3 Are the applicable SAP Analytical Summaries reviewed to determine the whether or not filter samples must be ashed?	NA	NA	
6.8.3.1 Are cassettes examined for loose material?	NA	NA	
6.8.3.1.1 If loose material or uneven loading is not evident, is a portion of the air samples retained?	NA	NA	
6.8.3.1.2 If loose material is evident, is the loose material filtered along with the air filter?	NA	NA	
6.8.3.2 Ashing (if applicable):			
6.8.3.2.1 Are filters covered with aluminum foil and placed in a plasma asher?	NA	NA	
6.8.3.2.2 Is the plasma asher operated at minimum power?	NA	NA	
6.8.3.2.3 Is 100% ashing confirmed by visual observation?	NA	NA	
6.8.3.3 Are air filters, loose material, dust, or ash, rinsed into a beaker and brought to a final volume of 100 mL with particle-free water?	NA	NA	
6.8.3.3.1 Adjusted to a pH of 3-4 with a 10% solution of glacial acetic acid?	NA	NA	
6.8.3.3.2 Sonicated for 3 minutes and allowed to settle for 2 minutes prior to filtering?	NA	NA	
6.8.3.4 Are the appropriate aliquots of filtrate passed through a disposable 25 mm filter assembly with a 0.2 µm MCE filter with a 5.0 µm MCE support pad?	NA	NA	
6.8.4 Are serial dilutions performed as necessary?	NA	NA	
6.8.5 Are TEM grids prepared as described in Section 6.7 of this checklist?	NA	NA	

Additional Comments:

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6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	Yes	No	Comments
6.9 Water Sample Preparation			
6.9.1 What method(s) does the laboratory use to prepare water samples for TEM analysis:			
6.9.1.1 EPA Method 100.2 - Determination of Asbestos Structures Over 10 µm in Length in Drinking Water?	NA	NA	
6.9.1.2 EPA Method 100.1 - Determination of Asbestos Fibers Drinking Water?	NA	NA	
6.9.1.3 Others (describe)? _____	NA	NA	
6.9.2 Are samples received and filtered by the laboratory within 48 hours of collection?	NA	NA	
6.9.2.1 If not, are they stored in a refrigerator until filtered?	NA	NA	
6.9.3 Laboratory Modification LB-000020A:			
6.9.3.1 Do samples undergo treatment with ozone/UV light?	☒	☐	
6.9.3.2 Are samples hand-agitated and sonicated?	☒	☐	
Refer to Section 6.2 of EPA Method 100.1			
6.9.4 Are the appropriate aliquots of the original sample poured though a 25 mm or 47 mm MCE filter (0.22 µm or smaller pore size) with an MCE filter (5 µm pore size) backing pad? Note: No less than 1 mL must be used as an aliquot.	NA	NA	
6.9.5 Are TEM grids prepared as described in Section 6.7 of this checklist?	NA	NA	

Additional Comments:

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6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	Yes	No	Comments
6.10 OU3 Tree Bark Sample Preparation			
6.10.1 Are the applicable Libby guidance documents available for reference:			
6.10.1.1 EPA-Libby-2012-12 – Sampling and Analysis of Tree Bark for Asbestos?	NA	NA	
6.10.2 Drying and Ashing:			
6.10.2.1 Are the diameter and thickness of the tree bark samples measured and recorded to an accuracy of ± 2mm?	NA	NA	
6.10.2.2 Is the entire tree bark sample weighed and placed in an oven for drying?	NA	NA	
6.10.2.2.1 Dried at 80º C until the weight stabilizes, a minimum of 6 hours, and weighed?	NA	NA	
6.10.2.3 Is the bark sample then covered and placed in a muffle furnace at 450º C for 18 hours, or until all organic matter has been removed, and weighed?	NA	NA	
6.10.2.3.1 Is the furnace ramped from 0º F to 450º C?	NA	NA	
6.10.3 Acid Treatment:			
6.10.3.1 After adding approximately 1-2 mL of DI water, is 10-20 of concentrated HCL added until no further reaction is visible (approx. 3-5 minutes)?	NA	NA	
6.10.3.2 Are samples diluted, transferred to a 100 mL container (with lid) and brought to a final volume of 100 mL with fiber-free DI water?	NA	NA	
6.10.3.3 Are samples capped, inverted 5-6 times, and sonicated for 2 minutes in preparation for filtering?	NA	NA	
6.10.4 Filtration:			
6.10.4.1 Are 5-20 mLs of solution transferred to a second container and brought to a volume of 100 mL with fiber-free DI water?	NA	NA	
6.10.4.2 Are dilutions agitated (inverted 5-6 times) and filtered through a 47 mm MCE filter (0.45 µm pore size)?	NA	NA	
6.10.4.2.1 Are additional dilutions prepared if the loading on the filter appears either too heavy (> 20%) or too light?	NA	NA	
6.10.5 Are TEM grids prepared as described in Section 6.7 of this checklist?	NA	NA	

Additional Comments:

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6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	Yes	No	Comments
6.11 OU3 Duff Sample Preparation			
6.11.1 Are the applicable Libby guidance documents available for reference:			
6.11.1.1 EPA-Libby-2012-11 – Sampling and Analysis of Duff for Asbestos?	NA	NA	
6.11.2 Drying and Ashing:			
6.11.2.1 Are the appropriate number of aluminum trays weighed and tared?	NA	NA	
6.11.2.1.1 For tracking purposes, is each tray marked with a unique number?	NA	NA	
6.11.2.2 Are trays filled to approximately ¾, dried at 60º C until the weight stabilizes a minimum of 10 hours, and weighed?	NA	NA	
6.11.2.3 Are dried duff samples transferred to covered pans and placed in a muffle furnace at 450º C for 18 hours, or until all organic matter has been removed, and weighed?	NA	NA	
6.11.2.4 Are ashed samples transferred to Zip-lock bags and homogenized?	NA	NA	
6.11.2.4.1 If an individual sample was split between multiple trays, was it combined into one Zip-lock bag?	NA	NA	
6.11.3 Acid Treatment:			
6.11.3.1 After adding approximately 1-2 mL of DI water to 0.25 grams (measured to ± 0.01 g) of ashed sample, is 10-20 mL of concentrated HCL added until no further reaction is visible (approx. 3-5 minutes)?	NA	NA	
6.11.3.2 Are samples diluted, transferred to a 100 mL container (with lid) and brought to a final volume of 100 mL with fiber-free DI water?	NA	NA	
6.11.3.3 Are sample capped, inverted 5-6 times, and sonicated for 2 minutes in preparation for filtering?	NA	NA	
6.11.4 Filtration:			
6.11.4.1 Is 0.1 to 1.0 mL of solution transferred to a second container and brought to a volume of 100 mL with fiber-free DI water?	NA	NA	
6.11.4.2 Are dilutions agitated (inverted 5-6 times) and filtered through a 47 mm MCE filter (0.45 µm pore size)?	NA	NA	
6.11.4.2.1 Are additional dilutions prepared if the loading on the filter appears either too heavy (> 20%) or too light?	NA	NA	
6.11.5 Are TEM grids prepared as described in Section 6.7 of this checklist?	NA	NA	

Additional Comments:

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6.0 TRANSMISSION ELECTRON MICROSCOPY (TEM) GRID PREPARATION	Yes	No	Comments
6.12 Grid Preparation/filtrate Storage			
6.12.1 For indirect preparations, are remaining filtrates filtered onto the appropriate filter(s) to be archived?	NA	NA	
6.12.2 Are all remaining filters and filter portions labeled prior to archiving?	NA	NA	
6.12.3 Are grids stored in marked grid storage boxes or other suitable containers and stored in a dust/fiber free environment?	NA	NA	
6.12.4 Is the location of grid preparation recorded in such a manner that they can be retrieved upon request in a timely manner?	NA	NA	
6.13 Quality Control Samples			
6.13.1 Are quality control samples prepared at the described frequency:			
6.13.1.1 Are laboratory blanks (LB) prepared at a frequency of 4% or with each preparation batch, whichever is more frequent?	NA	NA	
6.13.1.2 Are re-preparations prepared at a frequency of 1%?	NA	NA	
6.14 Standard Operating Procedures (SOPs)			
6.14.1 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?	NA	NA	

Document Title	Control No.	Description

6.15 Document Control	Yes	No	Comments
6.15.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?	NA	NA	

Document Title	Description/Comments

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

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7.0 TEM ANALYSIS	Yes	No	Comments
7.1 Are TEM areas adequate, clean, and orderly?	☒	☐	
7.2 Are steps taken to prevent the cross-contamination of equipment, supplies, and reagents?	☒	☐	

Personnel Interviewed

Name	Title	Experience
Leslie McClusky-Eissing	TEM Analyst	1 Year

7.3 Methods and Guidance Documents	Yes	No	Comments
7.3.1 What method(s) does the laboratory use to analyze samples TEM:			
7.3.1.1 40 CFR, Chapter 1, Part 763, Subpart E (AHERA)?	☒	☐	
7.3.1.2 ISO 10312:1995 E - Determination of Asbestos Fibers?	☒	☐	
7.3.1.3 ASTM D 5755-09 - Microvacuum Sampling and Indirect Analysis of Dust by TEM?	☒	☐	
7.3.1.4 EPA Method 100.2 - Determination of Asbestos Structures Over 10 µm in Length in Drinking Water?	☒	☐	
7.3.1.5 Others (list)? _____	☐	☒	
7.3.2 Are project-specific requirements communicated to laboratory personnel and available for reference:			
7.3.2.1 Laboratory Modifications?	☒	☐	Quality documents reside in the CDM eRoom, to which all EMSL analysts have access.
7.3.2.2 Project-specific SOPs?	☒	☐	
7.3.2.3 SAP Analytical Summaries?	☒	☐	
7.3.2.4 Project-specific Electronic Data Deliverables (EDDs)?	☒	☐	
7.3.2.5 Other (list)? _____	☐	☒	
7.4 TEM Instrumentation			
7.4.1 Does TEM instrumentation meet the following requirements:			
7.4.1.1 Capable of being operated at between 80 and 120 kV?	☒	☐	
7.4.1.2 Electron diffraction (ED) and energy dispersive X-ray (EDX) capabilities?	☒	☐	
7.4.1.3 Fluorescent screen with an inscribed or overlaid calibrated scale?	☒	☐	
7.4.2 Are the instruments equipped with thin film or beryllium windows (list below if necessary)? Beryllium & Light Element	☒	☐	
7.4.3 Are all routine and non-routine maintenance activities recorded in instrument-specific logbooks?	☒	☐	All maintenance is recorded on an electronic spreadsheet.

Instrument No.	Make	Model	Capabilities
04-01	JOEL	JEM-100CX II	Digital picture capabilities/Light Element
04-03	JOEL	JEM-200X	Digital picture capabilities/Beryllium
04-05	JOEL	JEM-100CX II	Digital picture capabilities/Light Element

Additional Comments:

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7.0 TEM ANALYSIS	Yes	No	Comments
7.5 Instrument Calibration (Laboratory Modification LB-00085A)			
7.5.1 Is microscope alignment performed daily:			
7.5.1.1 Centering of electron beam?	☒	☐	
7.5.1.2 Electron beam is properly stigmated on either side of crossover?	☒	☐	
7.5.1.3 Image properly focused?	☒	☐	
7.5.2 Is the TEM screen magnification calibrated monthly?	☒	☐	
7.5.3 Is the camera constant calibrated monthly?	☒	☐	Weekly
7.5.4 Is the spot size diameter determined to be less than 250 nm quarterly?	☒	☐	
7.5.5 Is the low beam dose (>= 15 seconds for Chrysotile) verified quarterly?	☒	☐	
7.5.6 EDXA System:			
7.5.6.1 Is X-ray energy versus channel for two peaks (i.e., Cu/Al) checked daily?	☒	☐	
7.5.6.2 Is detector resolution (Mn) checked quarterly?	☒	☐	
7.5.6.3 Are K-factors relative to Si determined for Na, Mg, Al, Ca, and Fe quarterly?	☒	☐	
7.5.7 Are instrument calibration records maintained in instrument-specific logbooks?	☒	☐	All calibrations are recorded on an electronic spreadsheet.
7.6 Reference Materials			
7.6.1 Does the laboratory maintain a library of reference materials on asbestos and other fiber types?	☒	☐	
7.6.2 Are instrument-specific “LA” spectra available, posted near the TEM?	☒	☐	
7.7 Grid Acceptance/Rejection Criteria			
7.7.1 Grid preparation rejection criteria:			
7.7.1.1 The replica is too dark due to poor dissolution?	☒	☐	
7.7.1.2 Replica is doubled or folded?	☒	☐	
7.7.1.3 Replica has > 25% obscuration rejected?	☒	☐	
7.7.1.4 Replica has < 50 intact grid openings?	☒	☐	
Refer to Request for Modifications LB-000016H and LB-000031G			
7.7.2 Are samples associated with grids determined to be overloaded (>25%) re-prepped using the indirect-transfer technique described in SOP EPA-Libby-08?	☒	☐	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

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7.0 TEM ANALYSIS	Yes	No	Comments
7.8 Modifications to AHERA & ASTM D5755:			
7.8.1 Laboratory Modification LB-000031G:			
7.8.1.1 Are structures classified as fibers (F), bundles (B), clusters (C) or matrices (M)?	☒	☐	
7.8.1.2 Are the actual lengths and widths of fibers, bundles, clusters and matrices (M) recorded?	☒	☐	
7.8.1.3 For disperse matrices and clusters, is the length of the longest protruding structure recorded?	☒	☐	
7.8.1.4 Unless identified as a "close call" (LB-000066D), are NAMs not recorded?	☒	☐	
7.8.1.5 Is the designation "ND" used to document when no structures are detected in a grid opening?	☒	☐	
7.8.1.6 Are fibers, bundles, clusters and matrices only recorded they contain individual constituent fibers meeting the aspect ratio criterion?	☒	☐	
7.8.1.7 Are non-countable recorded, but not counted, for informational purposes?	☒	☐	
7.8.1.8 Is the entire length recorded for structures originating in one grid opening and extending to an adjacent grid opening?	☒	☐	
7.8.2 Laboratory Modification LB-000067:			
7.8.2.1 Are the structure identification codes described in Tables D.1 and D.2 of ISO Method 10312 used?	☒	☐	
7.9 Modifications to EPA Method 100.2:			
7.9.1 Laboratory Modification LB-000020:			
7.9.1.1 Are all applicable analyte structures, including those comprising the LA complex, ≥ 0.5 µ in length with a ≥ AR recorded?	☒	☐	
7.9.1.2 Are a maximum of 10 grid openings counted?	☒	☐	
7.9.2 Laboratory Modification LB-000067:			
7.9.2.1 Are the structure identification codes described in Tables D.1 and D.2 of ISO Method 10312 used?	☒	☐	

Additional Comments:

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7.0 TEM ANALYSIS	Yes	No	Comments
7.10 Modifications to ISO Method 10312:			
7.10.1 Laboratory Modification LB-000016H:			
7.10.1.1 Unless identified as a “close call” (LB-000066D), are NAMs recorded?	☒	☐	
7.10.1.2 Are bundles only recorded if they contain individual constituent fibers meeting the aspect ratio criterion?	☒	☐	
7.10.1.3 Are bundles, compact clusters, and compact matrices counted regardless of aspect ratio?	☒	☐	
7.10.1.4 Are structures that intersect non-countable grid bars recorded for informational purposes?	☒	☐	
7.10.1.5 Are component structures, which do not intersect non-countable grid bars, but are within non-countable structures counted?	☒	☐	
7.10.1.6 Is the entire length recorded for structures originating in one grid opening and extending to an adjacent grid opening?	☒	☐	
7.10.1.7 For structures which intersect more than one grid bar is the observed length of the structure recorded?	☒	☐	
7.10.1.8 Are the recorded rules for partially obscured structures properly applied (i.e., MFO and MBO)?	☒	☐	
7.10.1.9 Are the counting and recording rules for the identification of PCMe structures at “low magnification” applied?	☒	☐	
7.11 Common TEM Modifications:			
7.11.1 Laboratory Modification LB-000030:			
7.11.1.1 Are highly detailed sketches of up to 50 asbestos structures provided?	☒	☐	
7.11.2 Laboratory Modification LB-000066D:			
7.11.2.1 Is the presence or absence of sodium and potassium recorded for all LA, OA and NAM particles (NaK, NaX, XK or XX)?	☒	☐	
7.11.2.2 Is probable mineral identification code recorded for all particles?	☒	☐	
7.11.2.2.1 Are LA particles identified as WRTA, AC, TR or AT?	☒	☐	
7.11.2.2.2 Are OA particles identified as AM, AN or CR?	☒	☐	
7.11.2.2.3 Are NAMs indicated as PY, OT or UN?	☒	☐	
7.11.2.3 Is one SAED pattern recorded for each amphibole asbestos type encountered per samples?	☒	☐	
7.11.2.4 Are EDS spectrum (a maximum of 5) collected for up to 5 LA and 5 Close-call NAM per sample?	☒	☐	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

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7.0 TEM ANALYSIS	Yes	No	Comments
7.12 Counting/stopping rules:			
7.12.1 Are the Analytical Summaries reviewed to determine the following:			
7.12.1.1 Analytical Sensitivity?	☒	☐	
7.12.1.2 Recording rules (i.e., AR)?	☒	☐	
7.12.1.3 Stopping rules (i.e., abundant CH)?	☒	☐	
7.12.1.4 Applicable Laboratory Modifications?	☒	☐	
7.12.1.5 Investigative or non-investigative?	☒	☐	
7.13 Quality Control Analyses (Laboratory Modification LB-000029C)			
7.13.1 Are quality control samples analyzed at the required frequencies:			
7.13.1.1 Laboratory blanks – Frequency 4%?	☒	☐	
7.13.1.2 Recount Same (RS) - Frequency of 1%?	☒	☐	
7.13.1.3 Recount Different (RD) - Frequency of 2.5%?	☒	☐	
7.13.1.4 Inter-laboratory - Frequency of 0.5%?	☒	☐	
7.13.1.5 Verified Analysis (VA) - Frequency of 1%?	☒	☐	
7.13.1.6 Re-preparations – Frequency of 1%	☒	☐	
7.13.2 Are samples selected for RS, RD and VA analyses in accordance with Laboratory Modification LB-000029C?	☒	☐	
7.13.3 Is the procedure used to evaluate QC sample analyses in accordance with Laboratory Modification LB-000029C?	☒	☐	
7.14 Standard Operating Procedures (SOPs)			
7.14.1 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?	☒	☐	All SOPs are available on the laboratory network.

Document Title	Control No.	Description

7.15 Document Control	Yes	No	Comments
7.15.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?	☒	☐	

Document Title	Description/Comments
Daily Calibration Log	Top loading balance.

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

USEPA Date(s) of On-site: 10/08/2013

8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.1 Are PLM areas adequate, clean, and orderly?	☒	☐	
8.2 Are steps taken to prevent the cross-contamination of equipment, supplies, and reagents?	☒	☐	
Personnel Interviewed			

Name	Title	Experience
Garret Vliete	PLM Supervisor	3 Years
Melissa Klinedinst	Laboratory QC Group Leader	6 Years
Leslie McClusky-Eissing	PLM Analyst	3 Years

8.3 Methods and Guidance Documents	Yes	No	Comments
8.3.1 Are the applicable guidance documents available for reference:			
8.3.1.1 EPA SOP SRC-Libby-01?	☒	☐	
8.3.1.2 EPA SOP SRC-Libby-03?	☒	☐	
8.3.1.3 NIOSH 9002, Issue 2 - Asbestos (Bulk) by PLM?	☐	☒	
8.3.1.4 Others (list)?	☒	☐	EPA 600
8.3.2 Are project-specific requirements communicated to laboratory personnel and available for reference:			
8.3.2.1 Laboratory Modifications?	☒	☐	Quality documents reside in the CDM eRoom, to which all EMSL analysts have access.
8.3.2.2 Project-specific SOPs?	☒	☐	
8.3.2.3 SAP Analytical Summaries?	☒	☐	
8.3.2.4 Project-specific Electronic Data Deliverables (EDDs)?	☒	☐	
8.3.2.5 Other (list)?	☐	☒	
8.4 Equipment			
8.4.1 Ventilation Hoods:			
8.4.1.1 Checked routinely and recorded in a permanent logbook?	☒	☐	
8.4.2 Drying oven (optional):			
8.4.2.1 Checked routinely and recorded in a permanent logbook?	☒	☐	
8.4.3 Muffle furnace:			
8.4.3.1 Checked routinely and recorded in a permanent logbook?	☒	☐	

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.4.4 Analytical balances:			
8.4.4.1 Two balances:			
8.4.4.1.1 Accurate to 0.01 g, range of 0.01 to 1000 g?	☐	☒	Not necessary, SOP SRC-Libby-01 to be revised.
8.4.4.1.2 Accurate to 1 mg?	☒	☐	
8.4.4.2 Checked routinely and recorded in a permanent logbook?	☒	☐	
8.4.4.3 Calibrated within the last 12 months by a certified technician?	☒	☐	
8.5 Stereomicroscope			
8.5.1 Do stereomicroscopes meet the following requirements:			
8.5.1.1 Magnification range of 10X to 50X?	☒	☐	
8.5.1.2 Incandescent or fluorescent light source?	☒	☐	
8.6 Polarized Light Microscope			
8.6.1 Are PLMs equipped with the following:			
8.6.1.1 Light source and replacement bulbs?	☒	☐	
8.6.1.2 Binocular observation tube?	☒	☐	
8.6.1.3 Blue daylight filter?	☒	☐	
8.6.1.4 Oculars (10X)?	☒	☐	
8.6.1.5 Objectives: 10X, 20X and 40X (or similar)?	☒	☐	
8.6.1.6 10X dispersion staining objective?	☒	☐	
8.6.1.7 A 360 degree graduated rotating stage?	☒	☐	
8.6.1.8 Polarizer and analyzer aligned at 90 degrees to one another?	☒	☐	
8.6.1.9 Bertrand lens?	☒	☐	
8.6.1.10 Substage condenser with iris diaphragm?	☒	☐	
8.6.1.11 Accessory slot for compensator plate?	☒	☐	Refer to Finding No. 2 in the Audit Report
8.6.1.12 First order red (550 nanometer) compensator plate?	☐	☒	
8.6.1.13 Crosshair reticle?	☒	☐	
8.6.1.14 Adjustment tools?	☒	☐	
8.7 Are microscopes well-maintained, and are all routine and non-routine maintenance activities recorded in instrument-specific logbooks?	☒	☐	

Instrument No.	Make	Model	Capabilities
Station 10	Leica	DM750P	
Thirteen (13) additional PLM stations are available.			

Additional Comments:

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.8 Refractive Index Liquids			
8.8.1 What refractive index liquids are available:			
8.8.1.1 High dispersion RI liquids from 1.620 to 1.640?	☒	☐	1.625
8.8.1.2 1.550 high dispersion RI liquid?	☒	☐	
8.8.1.3 1.680 to 1.700 RI liquids?	☒	☐	
8.8.2 Are refractive index liquids checked daily for contamination?	☒	☐	Salt is used to check RIs, tools, etc.
8.8.3 Are refractive index (RI) liquids calibrated monthly using a refractometer or other means (describe)?	☒	☐	Quarterly and prior to PLM-VE or PLM-Grav analyses
8.9 Reference Materials			
8.9.1 Does the laboratory maintain a library of asbestos and non-asbestos reference materials:			
8.9.1.1 NIST SRM 1866b (Ch, Am and Cr)?	☒	☐	
8.9.1.2 NIST SRM 1867a (Tr, Ac, and An)?	☒	☐	
8.9.1.3 USGS LA PEs:	☒	☐	
8.9.1.3.1 LA 0.2% by mass?	☒	☐	
8.9.1.3.2 LA 1.0% by mass?	☒	☐	
8.9.1.3.3 Other (List)?	☐	☒	2.0 % LA
8.9.1.4 Controlled LA asbestos (USGS)?	☒	☐	
8.9.1.5 NIST testing round M12001 (winchite/richterite)?	☒	☐	
8.9.1.6 Non-asbestos (i.e., gypsum, calcite, and fiberglass)?	☒	☐	
8.10 PLM Calibration	**Yes**	**No**	**Comments**
8.10.1 Is PLM alignment performed daily:			
8.10.1.1 Alignment?	☒	☐	
8.10.1.2 Stage and objectives centered?	☒	☐	
8.10.1.3 Optic axis centered?	☒	☐	
8.10.1.4 Alignment of the upper/lower polars?	☒	☐	
8.10.1.5 Centered through substage condenser and iris diaphragm?	☒	☐	
8.10.2 Microscope adjustments verified and recorded prior to sample analyses?	☒	☐	

Additional Comments:

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.11 PLM Analysis by NIOSH Method 9002:			
8.11.1 Does the laboratory perform PLM analyses on samples received from the Libby Superfund site? ***If answered "No" precede to Section 8.11 of the checklist.***	☐	☒	
8.11.2 Are samples visually examined by stereomicroscope for the following: 8.11.2.1 Color? 8.11.2.2 Homogeneity? 8.11.2.3 Texture?	 ☐ ☐ ☐	 ☐ ☐ ☐	
8.11.3 Which of the following techniques are used to prepare samples for analysis: 8.11.3.1 Mortar & pestle? 8.11.3.2 Acid washing? 8.11.3.3 Ashing? 8.11.3.4 Solvents? 8.11.3.5 Other (list)?	 ☐ ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐ ☐	
8.11.4 For non-friable, organically bound samples requiring ashing and/or acid reduction, are all necessary weights and tare weights measured and recorded?	☐	☐	
8.11.5 Are slides prepared using the appropriate refractive index liquid(s) and scanned for asbestos fibers using the following optical properties: 8.11.5.1 Morphology? 8.11.5.2 Color? 8.11.5.3 Refractive indices? 8.11.5.4 Pleochroism? 8.11.5.5 Birefringence? 8.11.5.6 Extinction characteristics? 8.11.5.7 Sign of elongation? 8.11.5.8 Dispersion staining characteristics?	 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
8.11.6 Are the observed optical properties compared to Table 1 (Optical Properties of Asbestos Fibers) to determine the asbestos mineral present?	☐	☐	
8.11.7 Is a quantitative assessment of asbestos content made from both the gross and microscopic examinations?	☐	☐	
8.11.8 If no fibers are detected in a homogeneous samples are at least two additional slides prepared and analyzed prior to concluding no asbestos is present?	☐	☐	
8.11.9 Is at least one optical property recorded for fibers determined to be non-asbestos fibers?	☐	☐	
Additional Comments:			

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.12 PLM-VE (SOP SRC-Libby-03)			
8.12.1 Stereomicroscopic Examination:			
8.12.1.1 Are all sample preparation activities performed within a HEPA-filtered hood?	☒	☐	
8.12.1.2 Is the entire sample transferred to an asbestos-free substrate for examination?	☒	☐	
8.12.1.3 Is the entire sample examined for homogeneity and the presence of suspect fibers?	☒	☐	
8.12.1.4 Are suspect fibers removed with fine forceps and mounted in the appropriate RI liquid for PLM analysis?	☒	☐	
8.12.1.5 Are the stereomicroscopic findings recorded:			
8.12.1.5.1 Sample appearance?	☒	☐	
8.12.1.5.2 Estimated percentage of LA?	☒	☐	
8.12.1.5.3 Estimated percentage of other asbestos types?	☒	☐	
8.12.2 Determination of Ashing the Sample:			
8.12.2.1 Are soil sample containing a significant amount of artifacts ashed prior to being prepared for random PLM mounts?	☒	☐	
8.12.2.1.1 Are samples ashed in a muffle furnace at approximately 480°C?	☒	☐	
8.12.2.1.2 Are the necessary gravimetric measurements recorded for the determination of “Pre-ash percent asbestos”?	☒	☐	
8.12.3 Slide Preparation for PLM-VE:			
8.12.3.1 Are a minimum of five random sub-samples mounted in the appropriate RI liquid (1.620-1.640) for measurement of LA optical properties?	☒	☐	
8.12.4 Supplemental Stereomicroscopic Evaluation:			
8.12.4.1 Following the random slide mount preparation, is the container agitated to cause the particulate to settle and asbestos fibers sort to the surface?	☒	☐	
8.12.4.2 Is the sample re-examined and the fiber pick procedure repeated?	☒	☐	

Additional Comments:

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.12.5 Classification of Asbestos Mineral Type:			
8.12.5.1 Using PLM is entire area of each prepared slide examined for asbestos, non-asbestos and matrix material?	☒	☐	
8.12.5.2 Is positive identification determined from the following six optical properties:			
8.12.5.2.1 Habit?	☒	☐	
8.12.5.2.2 Color & pleochroism (if present)?	☒	☐	
8.12.5.2.3 Both alpha and gamma Refractive indices?	☒	☐	
8.12.5.2.4 Birefringence?	☒	☐	
8.12.5.2.5 Extinction angle?	☒	☐	
8.12.5.2.6 Sign of elongation (positive-slow or negative fast)?	☒	☐	
8.12.5.3 Based on the optical properties, is asbestos classified into one of three categories:			
8.12.5.3.1 Libby Amphibole (LA)?	☒	☐	
8.12.5.3.2 Other Amphibole (OA)?	☒	☐	
8.12.5.3.3 Chrysotile (CH)?	☒	☐	
8.12.5.4 Is at least one optical property recorded for observed non-asbestos fibers?	☒	☐	
8.12.6 Quantification of Asbestos Content:			
8.12.6.1 Is asbestos reported as either mass or area percent for LA?	☒	☐	
8.12.6.2 Are other, non-LA, asbestos types reported in area percent?	☒	☐	
8.12.6.3 Are reference materials used to aid in visual estimation:			
8.12.6.3.1 LA PE reference materials (0.2% or 1.0%)?	☒	☐	
8.12.6.3.2 Are visual estimates of greater than 1% LA performed using calibration standards made in-house from NIST SRMs and NIST PEs?	☒	☐	
8.12.7 Are calibrated visual estimates determined from both the detailed stereomicroscopic observations and examination of the total area for all five random slide mounts?	☒	☐	
8.12.8 Are LA results reported in the appropriate bin categories:			
8.12.8.1 Non-detects recorded as Bin A?	☒	☐	
8.12.8.2 Less than 0.2% LA recorded as Bin B1?	☒	☐	
8.12.8.3 Greater than 0.2%, but less than 1% recorded as Bin B2?	☒	☐	
8.12.8.4 Equal to or greater than 1% recorded as Bin C, with the percentage recorded as a whole number?	☒	☐	

Additional Comments:

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.13 PLM-GRAV (SOP SRC-Libby-01)			
8.13.1 Stereomicroscopic Examination:			
8.13.2 Is the entire sample weighed and placed in an appropriate container?	☒	☐	
8.13.3 Does the stereomicroscopic examination include:			
8.13.3.1 Examination of multiple fields of view over the entire sample?	☒	☐	
8.13.3.2 Probing of the sample and breaking clumps where possible?	☒	☐	
8.13.3.3 Manipulation of the sample with the appropriate tools?	☒	☐	
8.13.3.4 Observation homogeneity, texture, friability, color and extent of any asbestos content?	☒	☐	
8.13.4 Doe the analyst refrain from segregating and weighing particles smaller than 2 - 3 mm (1/10 inch)?	☒	☐	
8.13.5 If no particles larger than 2 – 3 mm or larger are present, are one of the following recorded:			
8.13.5.1 No asbestos detected (ND)?	☒	☐	
8.13.5.2 Trace levels of asbestos observed, but not quantified (Tr)?	☒	☐	
8.13.6 Examination by PLM:			
8.13.7 Are tentatively identified asbestos particles examined by PLM as described in SOP SRC-Libby-03 (Section 8.12 of this checklist)?	☒	☐	
8.13.8 If asbestos particles are determined to be OA, are they further characterized:			
8.13.8.1 Amosite (AMOS)?	☒	☐	
8.13.8.2 Anthophylite (ANTH)?	☒	☐	
8.13.8.3 Crocidolite (CROC)?	☒	☐	
8.13.8.4 Unknown (UNK)?	☒	☐	
8.13.9 Is the total weight of each type of positively identified asbestos measured and recorded?	☒	☐	
8.13.10 Record Keeping:			
8.13.11 Is the data log sheet provided in Attachment 1 of the SOP used to record weights the initial (coarse fraction) and segregated asbestos?	☒	☐	

Additional Comments:

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8.0 POLARIZED LIGHT MICROSCOPY (PLM)	Yes	No	Comments
8.14 Quality Control Analyses			
8.14.1 Are the following types of QC analyses performed at the required frequencies:			
8.14.1.1 Laboratory duplicate self-check (LDS) at a frequency of 2%?	☒	☐	
8.14.1.2 Laboratory duplicate cross-check (LDC) at a frequency of 8%?	☒	☐	
8.14.2 For sample containing LA, are LDS and LDC analyses considered acceptable if:			
8.14.2.1 For LA results, within 1 Bin category?	☒	☐	
8.14.2.2 For LA results, %LA ≤1%?	☒	☐	
Note: For LA results greater than 1%, the laboratory should refer to their internal QA/QC system.			
8.14.3 Is the appropriate correction action taken when LDC or LDS analyses do not meet acceptance criteria (describe)?	☒	☐	
8.15 Standard Operating Procedures (SOPs)			
8.15.1 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?	☐	☒	Refer to Finding No. 2 in the Audit Report

Document Title	Control No.	Description

8.16 Document Control	Yes	No	Comments
8.16.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?	☒	☐	

Document Title	Description/Comments

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

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9.0 DATA MANAGEMENT	PCM	TEM	PLM	Comments
9.1 Data Package Review and Assembly	**Yes**	**Yes**	**Yes**	
9.1.1 Are deliverables reviewed to ensure project-specific requirements are adhered to:				
9.1.1.1 Request for Modifications to Laboratory Activities?	NA	☒	☒	Quality documents reside
9.1.1.2 Project-specific SOPs?	NA	☒	☒	in the CDM eRoom, to
9.1.1.3 SAP Analytical Summaries?	NA	☒	☒	which all EMSL analysts
9.1.1.4 Project-specific Electronic Data Deliverables (EDDs)?	NA	☒	☒	have access.
9.1.1.5 Other (list)? _____	NA	☐	☐	
9.1.2 Are all deliverables reviewed for completeness and accuracy prior to being submitted:				
9.1.2.1 Hard copy deliverables?	NA	☒	☐	Refer to Finding No. 3 in
9.1.2.2 Electronic deliverables?	NA	☐	☒	the Audit Report
9.1.3 Are all reviews documented?	NA	☒	☒	
9.2 Data Submission				
9.2.1 Is the submittal of electronic deliverables tracked and recorded:				
9.2.1.1 Date submitted?	NA	☒	☒	
9.2.1.2 Recipient?	NA	☒	☒	
9.2.2 Is the submittal of hard copy deliverables tracked and recorded:				
9.2.2.1 Date submitted?	NA	☒	☒	
9.2.2.2 Recipient?	NA	☒	☒	
9.3 Data Storage and Archiving				
9.2.3 Are electronic files archived onto suitable media on a frequent basis? How often? _____	NA	☒	☒	
9.2.4 Are all hardcopy data stored in a secured location with limited access (e.g., locking file cabinet)?	NA	☒	☒	Stored off-site in a secure facility

Additional Comments:

LIBBY-SPECIFIC ASBESTOS LABORATORY ON-SITE AUDIT CHECKLIST

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10.0 QUALITY ASSURANCE/QUALITY CONTROL	PCM	TEM	PLM	Comments
10.1 Laboratory Certifications	**Yes**	**Yes**	**Yes**	
10.1.1 Is the laboratory accredited for asbestos analysis under the National Voluntary Laboratory Accreditation Program (NVLAP):				
10.1.1.1 Asbestos Fiber Analysis (TEM Method)?	NA	☒	NA	2010, expires 10/2012
10.1.1.2 Asbestos Fiber Analysis (PLM Method)?	NA	NA	☒	2010, expires 10/2012
10.1.2 Is the laboratory accredited for asbestos analysis under the American Industrial Hygiene Association (AIHA), and does it participate in the National Institute for Occupational Safety and Health (NIOSH) Proficiency Analytical Testing (PAT) Program?	☒	NA	NA	2012, expires 04/2012
10.2 Training				
10.2.1 Have all analysts undergone training on the proper usage of the equipment and instrumentation used in the respective areas?	NA	☐	☒	Refer to Finding No. 1 in the Audit Report.
10.2.2 Have all analysts demonstrated proficiency through the preparation and/or analysis of standards or samples of known values?	NA	☒	☒	
10.2.3 Are training records maintained in analyst-specific files?	NA	☒	☒	
10.3 Internal Audits				
10.3.1 Are internal audits conducted on an annual basis using an appropriate checklist?	NA	☒	☒	
10.3.1.1 Are internal audit reports available for review?	☒	☒	☒	
10.4 Corrective/Preventive Action:				
10.4.1 Can the laboratory demonstrate the sequence of problem identification, corrective action, and resumption of duties?	NA	☒	☒	
10.5 Quality Records				
10.5.1 Are SOPs available in the applicable areas for all laboratory-specific procedures?	NA	☒	☒	Network (eLink)
10.5.2 Does the laboratory have a Quality Assurance Manual/Plan?	NA	☒	☒	
10.5.3 Does the laboratory compile monthly quality assurance/quality control reports?	NA	☒	☒	
10.6 Environmental Controls/Laboratory Monitoring				
10.6.1 Does the laboratory conduct an environmental monitoring program?	NA	☒	☒	
10.6.2 Is quarterly air monitoring performed in all laboratory areas?	NA	☒	☒	
10.6.2.1 Are the collected samples analyzed by TEM with a target analytical sensitivity of 0.005 structures/cc?	NA	☒	☒	
10.6.2.2 If LA is detected, are the affected areas thoroughly cleaned and a new set of samples collected and analyzed? *Laboratory Modification LB-000085A*	NA	☒	☒	

Additional Comments: